

Applicant : James P. Koch
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Attorney's Docket No.: 01996-005001

In the claims:

The pending claims are as follows:

1. (Previously amended) A cervical cap comprising:
a rim member dimensioned to fit a patient's exocervix;
a cap dome extending from the rim member to cover the exocervix and having an opening to allow fluid flow out of the cap dome, the cap dome being custom-molded to substantially completely conform to the shape of the patient's cervix; and
a valve associated with the opening, constructed to allow outflow while preventing fluid flow into said cap dome.
2. (Previously amended) The cervical cap of claim 1 wherein the valve comprises a check valve sealingly positioned in said opening.
3. (Previously amended) The cervical cap of claim 1 wherein the valve comprises a membrane disposed over an outer surface of the dome and sealed to the cap dome in spaced regions.
4. (Cancelled)
5. (Original) The cervical cap of claim 2 wherein the check valve is a duckbill valve.
6. (Previously amended) The cervical cap of claim 1 wherein the valve comprises a collapsed tube valve.
7. (Cancelled)
8. (Previously amended) The cervical cap of claim 3 wherein the membrane has a thickness of less than 0.5 mm.

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9. (Original) The cervical cap of claim 8 wherein the membrane has a thickness of less than 0.25 mm.

10. (Previously amended) The cervical cap of claim 3 wherein the membrane comprises a silicone polymer.

11. (Original) The cervical cap of claim 1 wherein the rim includes circumferential ridges on its inner surface.

12. (Original) The cervical cap of claim 1 further comprising a portion that is impregnated or coated with a therapeutic agent and that is constructed to slowly release the therapeutic agent during use of the cap.

13. (Original) The cervical cap of claim 12 wherein said portion is removable.

14. (Original) The cervical cap of claim 13 wherein said portion is a removable ring that is press-fit onto the cap adjacent the rim.

15. (Original) The cervical cap of claim 12 wherein the therapeutic agent is selected from the group consisting of microbicides, spermicides, medications, and combinations thereof.

16. (Original) The cervical cap of claim 12 wherein the therapeutic agent is an iodine complex.

17. (Previously amended) A cervical cap comprising (a) a cap body that is constructed to cover the exocervix and prevent ingress of sperm and fluids and includes a cap dome that is custom-molded to substantially completely conform to the shape of the patient's cervix, (b) a rim member, dimensioned to fit a patient's exocervix, from which the cap body extends, and (c) a portion, associated with the cap body, that is impregnated or coated with a therapeutic agent and is constructed to release the therapeutic agent over a period of time during use of the cap.

18. (Cancelled)

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19. (Previously amended) The cervical cap of claim 17 wherein said portion comprises a removable ring that is press-fit onto the cap adjacent the rim.

20. (Original) The cervical cap of claim 17 wherein the therapeutic agent is selected from the group consisting of microbicides, spermicides, medications, and combinations thereof.

21. (Original) The cervical cap of claim 17 wherein the therapeutic agent is an iodine complex.

22. (Original) The cervical cap of claim 17 wherein the therapeutic agent functions as both a spermicide and a microbicide.

23. (Currently amended) A method of protecting the exocervix of a female, comprising applying to the exocervix a custom molded cervical cap comprising (a) a cap body that includes a cap dome that is custom-molded to substantially completely conform to the shape of the patient's cervix, and is constructed to cover the exocervix and prevent ingress of sperm and fluids, (b) a rim member dimensioned to fit a patient's exocervix; and [(b)] (c) a portion that is impregnated or coated with a therapeutic agent, the portion being constructed to slowly release the therapeutic agent during use of the cap.

24. (Original) The method of claim 23 further comprising applying the portion to the cervical cap so that it will be removable.

25. (Original) The method of claim 24 further comprising instructing the female as to when the removable portion should be replaced.

26. (Original) The method of claim 24 wherein the portion comprises a removable ring and the method further comprises press-fitting the ring onto an outer surface of the cervical cap.

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27. (Original) The method of claim 23 wherein said therapeutic agent is selected from the group consisting of spermicides, microbicides, medications, and combinations thereof.

28. (Original) A method of measuring the diameter of an exocervix of a patient comprising the steps of:

(a) providing a ring gauge comprising a plurality of ring members having different diameters, means for positioning a selected ring member on the patient's exocervix;

(b) inserting the ring gauge, with one of the ring members, having a first diameter, attached thereto, into the vagina of the patient;

(c) positioning the ring member around the patient's exocervix and determining whether the rim member fits the exocervix; and

(d) repeating steps (a) - (c) with ring members having different diameters until a ring members is chosen which fits the exocervix, the diameter of this ring corresponding to the diameter of the patient's exocervix.

29. (Original) A method of claim 28 wherein the positioning means comprises a pair of elongated members adapted to be removably and rotatably attached to the ring member.

30. (Original) A method of claim 28 wherein the gauge further includes a measuring means for measuring the depth of the exocervix, and said method further includes the step of (c) positioning the measuring means to determine the depth of the exocervix.

31. (Original) A method of claim 30 wherein the positioning means comprises a pair of elongated members adapted to be removably and rotatably attached to the ring member and the measuring means comprises a measuring member movably mounted on one of the elongated members.

32. (Original) A method of claim 28 further comprising the steps of, prior to inserting the ring gauge:

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- (a) inserting a cervical plunger, having a plunger member and a tube member in fluid communication with the plunger member;
- (b) placing the cervical plunger on the exocervix;
- (c) drawing a vacuum through the tube member to draw the exocervix against an inner surface of the plunger member; and
- (d) positioning the cervix by moving the tube member.

33. (Previously amended) A kit for use by a clinician in forming a custom cervical cap in situ, in a patient's body, comprising in combination a rim member dimensioned to fit an exocervix, the rim member including a substantially ring-shaped surface that, when the rim member is placed on the exocervix, faces toward the opening of the patient's vagina, a curable material, and a means for applying the curable material to the ring-shaped surface.

34. (Previously amended) A kit for use by a clinician in forming a custom cervical cap in situ, in a patient's body, comprising in combination a rim member dimensioned to fit an exocervix, a shell member dimensioned to be mounted on said rim member, a curable material, and a means for applying the curable material.

35. (Original) A kit of claim 34 wherein the shell member has an aperture.

36. (Original) A kit of claim 34 wherein the shell member has at least one tube.

37-38. (Cancelled)

39. (Original) A kit of claim 34 further comprising a cervical plunger.

40. (Original) A kit of claim 35 further comprising a cervical plunger.

41. (Original) The cervical cap of claim 17 further comprising a valve constructed to allow outflow from the cap body while preventing fluid flow into said cap body.

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42. (Original) The cervical cap of claim 41 wherein said valve is selected from the group consisting of check valves and collapsed tube valves.

43. (Original) The cervical cap of claim 41 wherein said valve comprises a membrane disposed over an outer surface of the cap body.

44. (Previously added) The cervical cap of claim 2 wherein the valve further comprises a thin membrane disposed over an outer surface of the cap dome and sealed to the cap dome in spaced regions.

45. (Previously added) The cervical cap of claim 2 wherein the valve further comprises a collapsed tube valve.

46. (Previously added) The cervical cap of claim 1 wherein the cap dome comprises a cured polymeric material.

47. (Previously added) The cervical cap of claim 17 wherein said portion is removable.

48. (Previously added) The cervical cap of claim 47 wherein said portion is replaceable.

49. (Previously added) The kit of claim 33 further comprising a ring gauge.

50. (Previously added) The kit of claim 34 further comprising a ring gauge.

51-56. (Cancelled)

57. (Previously added) A kit for use by a clinician in forming a custom cervical cap in situ, in a patient's body, comprising in combination a rim member dimensioned to fit an exocervix, a ring gauge, a curable material, and a means for applying the curable material.

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58. (Previously added) A cervical cap comprising:
a snugly fitting rim member dimensioned to fit a patient's exocervix;
a cap dome, bonded to the rim member, the cap dome being configured to cover the
exocervix and being custom-molded to substantially completely conform to the shape of the
patient's cervix.

59. (Previously added) The cervical cap of claim 58 wherein the rim member comprises
one or more ridges configured to securely grip the exocervix.